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| 10/532,407 | 04/22/2005 | Adel Penhasi | 030231-0158 | 9132 |

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| EXAMINER | |
|---|---|
| WESTERBERG, NISSA M | |
| ART UNIT | PAPER NUMBER |
| 1618 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/532,407 | PENHASI ET AL. | |
| | Examiner | Art Unit | |
| | Nissa M. Westerberg | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-102* is/are pending in the application.

4a) Of the above claim(s) *1-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicants' arguments, filed February 12, 2010, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

### *Double Patenting*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 89, 91 and 93 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 43, 45 and 47 - 49 of copending Application No. 10/555310 in view of US Patent 5,840,332. This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed June 9, 2008, February 20, 2009, and August 10, 2009 and those set forth below.

Applicants request that this rejection be held in abeyance until patentable subject matter is identified. Therefore, this rejection is MAINTAINED for the reasons of record set forth previously in the above referenced Office Action.

### *Claim Rejections - 35 USC § 112- 1st Paragraph*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 89 – 102 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This written description rejection is MAINTAINED for the reasons set forth in the Office Actions mailed February 20, 2009 and August 10, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that the specification provides numerous working examples and accompanying figures that provide ample guidance allowing the skilled artisan to formulate the claimed venlafaxine delayed burst release formulations. The specification described in detail the various components of the inventive formulation and several working examples.

These arguments are unpersuasive. The breadth of the claims is not commensurate in scope with the working examples and ingredients set forth in the specification as to the various excipients falling within the broad classes recited in the claims (e.g., water insoluble hydrophobic carrier) and the amounts of the various ingredients that provide the claimed release profile. The examples set forth in the specification make use of limited number of excipients in similar amounts, while the claims are drawn to borad classes of compounds (e.g., disintegrant) and places no limitations on the amounts of these ingredients present. A description which renders the claimed invention obvious does not satisfy the written description provision (p 15 of

*Ariad Pharmaceuticals, Inc. v. Eli Lilly*, CAFC 2008-1248, decided March 22, 2010, citing *Lockwood V. Am. Airlines*, 1-7 F3d 1565, 1571-72 (Fed Cir. 1997)). The written description is sufficient regarding the examples which are set forth but beyond that, full possession of the claimed invention has not been established.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 89 – 99 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. (US 6,274,171) in view of Lerner et al. (US 5,840,332). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed June 9, 2008, February 20, 2009, and August 10, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that neither Sherman nor Lerner disclose a composition that would allow the delayed release burst of venlafaxine after a two hour lag time as claimed. Sherman does not disclose a burst release of drug, much less a delayed release as claimed. Table I shows a linear relationship between the percent release of venlafaxine hydrochloride as function of time over a 24 hour period. Working examples 6 and 7 does not show a burst release. This is in stark contrast to the formulation used in the inventive method that displays an initial burst of drug release approximately 3 hours after administration, a kinetic profile not exhibited by Sherman's formulation. The formulation of Lerner does not conform to the "burst kinetics" as claimed so modifying Sherman's formulation to include a water insoluble particulate matter disclosed by Lerner would still fail to allow the artisan to arrive at a formulation having the claimed delayed burst release.

These arguments are unpersuasive. The cited art need not explicitly disclose the claimed release profile or use the same motivation used by applicant in order to arrive

at the claimed composition. As stated previously, the same compositions must have the same properties. For dosage forms, the release profile is determined by the ingredients and structure (e.g., core with a coating). Applicants have not demonstrated that the formulations of the cited prior art, when directly compared to the compositions set forth in the instant application using the same dissolution test procedures, so not possess the claimed properties.

Reproduced below is table 1 (col 6) from Sherman et al.:

TABLE 1

Acceptable Coated Spheroid Dissolution Rates

| Time (hours) | Average % Venlafaxine HCl released |
|---|---|
| 2 | <30 |
| 4 | 30–55 |
| 8 | 55–80 |
| 12 | 65–90 |
| 24 | >80 |

This indicates that less than 30%, a range which includes zero, of the drug is released within 2 hours, not necessarily that approximately 30% of the drug is released within the first 2 hours as stated by Applicant. Applicants have also not claimed or defined the conditions under which the release is measures (just generic conditions of *in vivo* or *in vitro*) or provided a definition as to how large of drug release must occur to be deemed a “delayed burst release”. The data set forth in figure 2 of the instant application, for example, indicates that this is the release profile occurs after being placed in the more basic medium for preferential release in the colon whereas Sherman’s dissolution tests are carried out in purified water (col 6, ln 36 – 40). The *in vivo* release can be affected by factors such as if the medication is taken with food or on an empty stomach. It would

be obvious to one of ordinary skill in the art to optimize the various release percentages to provide optimal blood plasma levels of the drug.

As Applicants have not presented persuasive evidence that the compositions of the cited prior art, having the structure and ingredients as recited in the instant claims, do not have the claimed release profile, this rejection is maintained.

10. Claims 89 – 102 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. and Lerner et al. further in view of Upton et al. (US 5,506,270). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed February 20, 2009 and August 10, 2009 and those set forth herein.

Applicant traverses this rejection on the grounds that neither Sherman nor Lerner tech a formulation with burst release kinetics. Incorporation of the teachings of Upton still results in a formulation different from that is different from the formulation recited in the instant claims.

These arguments are unpersuasive. As discussed in greater detail above, as the composition that results from the combination of Sherman and Lerner has the same structure as recited in the instant claims, even though a burst release kinetic profile is not explicitly disclosed by the cited prior art. In the absence of evidence as to the different properties of these compositions from those recited in instant claims, this rejection is maintained for the reasons of record.

***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. This application contains claims 1 - 88 drawn to an invention nonelected with traverse in the reply filed on April 7, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW